UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

AFFIDAVIT OF RICHARD DOWLING

STATE OF NEW JERSEY)
) SS
COUNTY OF MORRIS)

1. My name is Richard Dowling. I was formerly the Director of Manufacturing Operations for Actavis Totowa LLC at the Little Falls, New Jersey facility ("Little Falls facility"). My current job title is Director of Manufacturing Compliance for the Actavis Totowa LLC Little Falls, New Jersey facility. I have been with Actavis Totowa since October, 2005.

2. From October, 2005, through May, 2008, I had responsibility for all manufacturing floor operations at the Little Falls facility. Because of my job responsibilities, I have personal knowledge of all aspects of the manufacture and production of Digitek® and of all the products Actavis Totowa has produced at the Little Falls facility since October, 2005, including: raw material storage, plant layout, blending processes, blend mixture storage, tablet compression, encapsulation, storage of tablets and capsules, and the cleaning and preventative maintenance of all of the equipment utilized by Actavis Totowa at the Little Falls facility in any aspect of these processes.

3. The information reflecting and relating to the cleaning of equipment used in the manufacturing process at the Little Falls facility is entered in equipment usage and cleaning "logs" that are created and maintained separately from manufacturing records for each batch of product manufactured at the facility. The records relating to the manufacture of a specific batch

of product would not include the logbook records relating to cleaning the equipment used during the production of that batch.

4. "Cleaning validation" issues refer generally to issues related to the process by which equipment is "wet" cleaned after being used to manufacture a campaign of a specific product and results are obtained for surface swab testing on the equipment for residual active pharmaceutical ingredient or cleaning detergent. "Out of specification" issues refer generally to issues relating to whether a drug product meets finished product testing release specifications in the Quality Control laboratory for that product. "Dosage strength" issues refer generally to issues of whether a drug product has the correct amount or potency of the proper active pharmaceutical ingredient for that product.

5. There is no connection between a "cleaning validation" issue associated with one drug product and a "dosage strength" issue associated with a different drug product. A cleaning issue might relate to possible cross-contamination of the ingredients used in two different products, but it could not be related to the issue of dosage strength of either product. For example, whether a piece of equipment used to manufacture aspirin was cleaned properly before being used to manufacture Digitek® could not impact whether the Digitek® was manufactured with the appropriate amount of digoxin, the active pharmaceutical ingredient in Digitek®.

FURTHER AFFIANT SAYETH NAUGHT.

Richard Dowling

RICHARD DOWLING

SWORN TO BEFORE ME AND SUBSCRIBED in my presence this 13th day of July, 2009.

NOTARY PUBLIC
Attorney at Law